Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Smart Nano-Wound Dressing for Wound Healing in Diabetic Patients: A Randomized Controlled Trial

Protocol summary

Study aim

This study aims to evaluate the efficacy of a synthesized nano-wound dressing in the treatment of diabetic wounds

Design

Study Procedure: Test Group: The surrounding area of the wound will be disinfected and cleaned (standard wound washing and controlled debridement). The nano-wound dressing will be applied to the wound, ensuring maximum contact with the wound surface. A suitable secondary dressing will be placed over the nano-wound dressing. The dressing will be changed every 2 to 3 days. The patient will be kept at room temperature to avoid direct sunlight exposure. Control Group: Standard wound dressings (gauze, foam, or hydrogel) will be used. Dressings will be changed every 2 to 3 days. All other wound care procedures will be the same as in the test group. Data Analysis: At the end of each stage, outcome evaluation and statistical analysis will be performed.

Settings and conduct

The study will be carried out as a double-blind, multicenter trial at institutions affiliated with Iran University of Medical Sciences and Bam University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18–80 years with diabetic wounds of varying grades and sizes between 1–15 cm^2, who have provided written informed consent for follow-up and demonstrate compliance with the use of the nano-wound dressing. Exclusion criteria: Participants who do not meet any of the above requirements or fail to comply during the study.

Intervention groups

Intervention group: Patients with diabetic wounds treated with the nano-wound dressing alongside standard wound care. Control group: Patients with diabetic wounds treated with the standard wound dressing alongside standard wound care.

Main outcome variables

Primary outcomes: Wound closure rate and wound healing duration.

General information

Reason for update

Acronym

SNWD-DM

IRCT registration information

IRCT registration number: **IRCT20250610066159N1**
Registration date: **2025-10-12, 1404/07/20**
Registration timing: **prospective**

Last update: **2025-10-12, 1404/07/20**
Update count: **0**

Registration date

2025-10-12, 1404/07/20

Registrant information

Name

Ghazaleh Chizarifard

Name of organization / entity

Bam University of Medical Sciences

Country

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-11-21, 1404/08/30

Expected recruitment end date

2026-11-21, 1405/08/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Smart Nano-Wound Dressing for Wound Healing in Diabetic Patients: A Randomized Controlled Trial

Public title
Investigation of the Effects of Lemon Balm (Melissa officinalis) on Diabetic Wounds
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with diabetic wounds Participants aged between 18 and 80 years Participants who demonstrate adequate compliance with the use of the wound dressing throughout the treatment period Participants who have provided written informed consent prior to enrollment
Exclusion criteria:
Not applicable
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were assigned to the treatment and control groups using block randomization (block size = 4) generated with R software. The randomization sequence was prepared and coded by a researcher not involved in the study execution. The trial was conducted in a double-blind manner, so that both participants and outcome assessors were unaware of group allocation. This study was designed as a multicenter, controlled, randomized clinical trial.
Blinding (investigator's opinion)
Double blinded
Blinding description
A stratified randomization method will be used. Patients will be divided into two groups based on the presence of diabetic wounds and whether they will receive the specialized dressing (intervention) or the standard dressing (control). Randomization within each group will then be performed using a pre-prepared randomization list. This list will be generated by the physician prior to the study. The principal investigator will introduce the selected patients to the clinical caregiver and the outcome assessor (a nursing specialist) responsible for the process. According to the list, wound treatment will be carried out using either the nano-wound dressing or the standard wound dressing
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Bam University of Medical Science
Street address
Shahid Rajaei Boulevard, Sardarān-e Shahid Square, Bam, Iran
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Province
Kerman
Postal code
38R9+498
Approval date
2025-05-18, 1404/02/28
Ethics committee reference number
IR.MUBAM.REC.1404.012

Health conditions studied

1

Description of health condition studied
Diabetic wound
ICD-10 code
E11.622
ICD-10 code description
Type 2 diabetes mellitus with other skin ulcer

Primary outcomes

1

Description
The primary outcome variable is wound healing, measured as the reduction in wound area in patients treated with the smart nano-wound dressing. Wound area will be assessed using graph paper measurement or digital imaging software at specified time points. Changes in wound area between the treatment and control groups will be compared as the main indicator of study efficacy.
Timepoint
Assessments will be conducted on days 0, 7, 14, and 28,

with the schedule extended as needed until complete wound healing.

Method of measurement

Wound evaluation will be performed through visual inspection and by measuring the wound surface area.

Secondary outcomes

empty

Intervention groups

1

Description

Smart nanofiber wound dressing containing 1% Melissa officinalis extract:Patients in the intervention group will use a smart nanofiber wound dressing containing 1% Melissa officinalis extract, produced by the company “Pajohesh Ba Ma”. The dressing will be changed every 6 days by a trained nurse. The total treatment duration is two weeks. During each dressing session, patients will receive the necessary training on wound care. Additional materials include bandage and adhesive tape.

Category

Treatment - Devices

2

Description

Control group: Standard wound dressing: https://chatgpt.com/c/68eb66d9-7538-832e-bb06-9d1e7e28e660#:~:text=Patients%20in%20the%20control%20group%20will%20use%20standard%20wound%20dressing.%20The%20dressing%20will%20be%20changed%20every%206%20days%20according%20to%20standard%20clinical%20guidelines.%20The%20total%20treatment%20duration%20is%20two%20weeks%2C%20and%20all%20patients%20will%20receive%20wound%20care%20education%20from%20a%20trained%20nurse.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Bam university of medical sciences

Full name of responsible person
Dr. Shirin Nasri Mohajeri

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Shahid Rajaei Boulevard, Sardarān-e Shahid Square, Bam, Iran

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Recruitment center

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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Pajoohesh BAMA Co

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Pajoohesh BAMA Co

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Pajooshesh BAMA Co.
Full name of responsible person
Dr. Ghazaleh Chizari Fard
Position
CEO
Latest degree
Ph.D.
Other areas of specialty/work
Medical Nanotechnology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Production of smart nanowound dressings in wound healing in diabetic patients: A randomized clinical trial
When the data will become available and for how long
1 year after the end of the clinical study
To whom data/document is available
Medical researchers
Under which criteria data/document could be used
For future studies in the field of wound healing and with permission from the project manager
From where data/document is obtainable
Permission must be obtained in writing from the project manager.

What processes are involved for a request to access data/document

1- Request access to the project implementer 2- Review by the implementer and the partner team 3- Approval of the request by the implementer 4- Permission to access the data

Comments